

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA,	*	
	*	
Plaintiff,	*	CIVIL NO. <u>MJG-11-0668</u>
V.	*	
	*	(False Claims Act Violation,
	*	31 U.S.C. § 3729(a)(1);
JOHN ARTHUR KIELY, M.D.,	*	False Claims Act Violation,
	*	31 U.S.C. § 3729(a)(1)(B),
Defendant	*	Common Law Fraud;
	*	Unjust Enrichment;
	*	Payment by Mistake;
	*	Disgorgement)
	*	
	*	

* * * * *

FIRST AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL

INTRODUCTION

1. Plaintiff, the United States of America ("United States"), on behalf of its agency, the Department of Health and Human Services ("HHS"), and HHS's component, the Center for Medicare and Medicaid Services ("CMS"), brings this civil action against the defendant, John Arthur Kiely, M.D., to recover losses from false claims submitted to HHS as a result of the fraudulent course of conduct of the defendant (hereinafter "Kiely"). Specifically, between October 29, 2002 and April 14, 2009, Kiely submitted or caused the submission of false claims to Medicare, Parts A and B, and Medicaid, resulting in the billing of these federal health care programs for Argon Laser Trabeculoplasties ("ALT") that were not medically necessary, and the repetition of which was destructive

rather than beneficial.

2. Kiely also billed Medicare and Medicaid for Lysis of Adhesion procedures ("LOA") that were neither actually performed nor medically necessary. Kiely billed LOAs to maximize the probability of ensuring payment that would likely have been denied if the procedure actually performed, namely, a Yag Capsulotomy, was billed. Kiely's fraudulent conduct in this regard resulted in the submission of false claims to Medicare Part B and Medicaid for Lysis of Adhesions that were not performed or medically necessary.

3. All of the above-identified procedures are treatments designed to address certain conditions affecting the eye. The fraudulent billing schemes committed by Kiely caused monetary losses to the Medicare Part A and B programs and Medicaid in an amount to be proven at trial. The United States further alleges the following:

NATURE OF THE ACTION

4. This action is brought pursuant to the False Claims Act ("FCA"), as amended, 31 U.S.C. §§ 3729-33, to recover treble damages, civil penalties, and all available damages for common law fraud, unjust enrichment, payment under mistake of fact and disgorgement.

5. This action is based upon the fact that Kiely knowingly submitted and caused the submission of false or fraudulent claims to the Medicare and Medicaid programs and knowingly made, used, or

caused the making or use of false records or statements to get false or fraudulent Medicare and Medicaid claims paid by HHS during the time-frame referenced above, resulting in the payment of money for services that were not medically necessary or rendered as represented.

JURISDICTION AND VENUE

6. The Court has subject matter jurisdiction over this statutory and common law action pursuant to 28 U.S.C. §§ 1331, 1345 and 1367(a).

7. Under 31 U.S.C. § 3732(a), the Court has personal jurisdiction over Kiely because he resides, has transacted business, and committed acts in this District in violation of 31 U.S.C. § 3729.

8. Venue is proper in the District of Maryland under 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a) because the acts committed by Kiely in violation of 31 U.S.C. § 3729 occurred in this District.

THE PARTIES

9. Plaintiff is the United States who brings this action on behalf of HHS and CMS, formerly known as the Health Care Financing Administration ("HCFA").

10. At all times relevant to this Complaint, Kiely was a licensed physician engaged in the practice of ophthalmology in the State of Maryland, specializing in the treatment of glaucoma and

cataract-related complications by way of laser surgery and doing business at several locations, including: 10 North Payson Street, Baltimore, Maryland 21223 (a clinic known variously as the Payson Street Clinic and Bon Secours Specialty Clinic and operated by Bon Secours Hospital).

11. At all times relevant to this Complaint, Kiely treated patients covered by the Medicare Part A and B programs and Medicaid, which programs are described in more detail below.

THE FEDERAL HEALTHCARE PROGRAMS

A. The Medicare Program

(1). Medicare Part A

12. Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg, established the Medicare program which provides medical insurance for covered services to any person 65 years or older, to certain disabled persons, and to individuals afflicted with end-stage renal disease who elect coverage under the program. 42 U.S.C. §§ 426, 426A.

13. HHS, as an agency of the United States, is responsible for the administration and supervision of the Medicare program. HHS has delegated the administration of the Medicare program to its component agency, CMS.

14. The Medicare program is comprised of four parts. Only Medicare Parts A and B are directly at issue in this case.

15. Part A of the Medicare program authorizes payment for

institutional care, including but not limited to hospital admissions. 42 U.S.C. §§ 1395c-1395i-4.

16. To participate in the Medicare program, a hospital must file a provider agreement with the Secretary of HHS. 42 U.S.C. § 1395cc. The provider agreement mandates compliance with the requirements that the Secretary of HHS considers necessary for participation in the program. *Id.* In addition to other limitations on coverage, Medicare covers only those services that are actually rendered and are "reasonable and medically necessary." 42 U.S.C. 1395y(a)(1)(A).

17. The United States provides reimbursement for Medicare claims, under both Part A and B of the Medicare program, through CMS. CMS, in turn, contracts with private insurance carriers, to administer, process, and pay Medicare claims. In this capacity, the carrier acts on behalf of CMS and receives, pays or rejects submitted claims based upon Medicare rules, regulations, and procedures.

18. Under Part A of the Medicare program, the amount that Medicare pays to a hospital for the treatment rendered at the hospital's institution is based in large part on the illness or condition that led to the patient's admission to the hospital or the patient's illness or condition that is principally treated by the hospital. Medicare also looks at whether the patient had other problems that were treated at the hospital; these other problems

are called "complications or co-morbidities" and are represented by a secondary diagnosis.

Submitting Claims for Medicare Part A Reimbursement

19. Upon discharge of Medicare beneficiaries from a hospital, the hospital submits claims for interim reimbursement for the items and services delivered to those beneficiaries during the hospital stay. 42 C.F.R. §§ 413.1, 413.60, 413.64.

20. When hospitals submit claims for treating Medicare inpatients, the claims contain code numbers representing the diagnoses for that patient. These code numbers are referred to as "ICD-9" codes and originate from a book called the "International Classification of Diseases, 9th Edition."

21. CMS has established a scale of payments to hospitals called "diagnostic related groups" ("DRGs"). When a Medicare claim is submitted, the Fiscal Intermediary assigns the ICD-9 codes listed by the hospital to the related DRG. In other words, each ICD-9 code usually corresponds to a particular DRG. The DRG determines how much the hospital is paid.

22. Hospitals are required to base the selected ICD-9 code upon the diagnostic statements of a patient's treating physician in that patient's medical record. 42 C.F.R. § 482.24©).

(2). Medicare Part B

23. Medicare Part B, established by Part B, Title XVIII of the Social Security Act under 42 U.S.C. §§ 1395j-1395w and more

formally known as the Supplementary Medical Insurance Program for the Aged and Disabled, is a 100% federally subsidized health insurance system for disabled persons who are 65 or older. Eligible persons aged 65 or more and persons with qualifying disabilities may enroll in the Medicare Part B program to obtain medical benefits in return for payments of monthly premiums in amounts established by HHS. The benefits covered by Medicare Part B include medical treatment and services performed by physicians. An enrolled beneficiary who obtains a covered medical service can either pay for the medical service himself, and request reimbursement of 80% of the reasonable charge, or assign the right to reimbursement to the physician providing the service, who collects payment as an assignee of the beneficiary under 42 U.S.C. § 1395(b)(3)(B)(ii). The funds to reimburse claims originate from the Medicare Trust Fund.

Submitting Claims For Medicare Part B Reimbursement

24. To obtain reimbursement pursuant to Medicare Part B, the physician seeking reimbursement must have complied with applicable statutes, regulations and guidelines. A provider therefore has a duty to have knowledge of the applicable statutes, regulations and guidelines regarding coverage for Medicare reimbursement. Those regulations and guidelines include, but are not limited to:

a. Billing Medicare for only reasonable and necessary medical services. 42 U.S.C. § 1395y(a)(1)(A);

b. Not making false statements or misrepresentations of material facts concerning requests for payment under Medicare. 42 U.S.C. § 1320a-7b(a)(1)&(2); 1320a-7; 1320a-7a;

c. Providing evidence that the service given is medically necessary. 42 U.S.C. § 1320c-5(a)(3);

d. Assuring that such services are not substantially in excess of the needs of such patients. 42 U.S.C. § 1320a-7b(6)&(8); and

e. Certifying, when presenting a claim for reimbursement, that the service provided is a medical necessity. 42 U.S.C. § 1395n(a)(2)(B).

25. Like the reimbursement process under Medicare Part A, HHS, through CMS, assigns the task of paying Part B claims from the Medicare Trust Fund to private insurance carriers. 42 U.S.C. § 1395u.

26. At all times relevant to this Complaint, HHS, through CMS, administered the Medicare Part B program in the State of Maryland through Trailblazer (hereinafter referred to as "the carrier"). The carrier reviewed and approved claims submitted for medical reimbursement by Medicare providers, including claims submitted or caused to be submitted by Kiely. The carrier then made payment on those claims which appeared to be eligible for reimbursement under the Medicare Part B program.

27. To obtain such payment, a physician is required to submit

claims to the carrier using forms known as CMS-1500s (formerly known as Medicare Health Insurance Claim Form, "HCFA Form-1500").

28. Part of the information the provider includes on a CMS-1500 claim form is a multi-digit code known as Current Procedural Terminology codes ("CPT codes"). The American Medical Association assigns and publishes these numeric codes and Health Care Financing Administration Common Procedure Coding System ("HCPCS") codes. The codes are a listing of procedures and services performed by health care providers. Health care providers include CPT Codes on the CMS-1500 claims form to identify the services rendered and for which reimbursement is sought. Health care benefit programs like Medicare use those specified codes in deciding whether to issue or deny payment. Each health care benefit program establishes a fee reimbursement for each procedure described by a CPT or HCPCS code. The carrier, on behalf of CMS, pays for a portion of the submitted claim.

29. Any provider seeking Medicare reimbursement through Part B must certify on the CMS-1500 claim form that the "services shown on this form were medically indicated and necessary for the health of the patient and were performed personally by me or were furnished incident to my professional service by my employee under my immediate personal supervision."

B. The Medicaid Program

30. Title XIX of the Social Security Act, 42 U.S.C. §§ 1396,

et seq., established the Medicaid program. Medicaid is a joint federal and state program that provides health care benefits for certain groups, primarily the poor and the disabled. The United States provides a significant share of the funding for the Medicaid program and also ensures that the states comply with certain standards in administering the program.

31. In the State of Maryland, and at times relevant to this Complaint, the federal government paid 50% of all Medicaid claims. 42 U.S.C. § 1396d(b).

32. The Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A).

33. By becoming a participating provider in the Medicaid program, providers agree to abide by all laws, regulations, and procedures applicable to that program, including those governing reimbursement.

34. Similar to the requirement for obtaining reimbursement through Medicare Part B, Medicaid pays providers for services actually rendered, as represented on the claim form, and services that are reasonable and medically necessary.

35. Providers who do not perform medically necessary services and the services identified on the claims form are not entitled to reimbursement from Medicare and Medicaid for those services.

THE FRAUDULENT CONDUCT COMMON TO ALL COUNTS

36. At all times relevant to this Complaint, Kiely was a provider of health care services to Medicare and Medicaid beneficiaries, having entered into provider agreements with HHS-CMS and the State of Maryland, respectively, to participate in each of those programs.

37. Under the terms of the Medicare provider agreement, Kiely agreed to comply with all of the conditions imposed upon him by applicable federal law and regulations, including the requirement that he submit claims for reimbursement only for services that were actually performed and medically necessary.

38. Kiely agreed to like terms pursuant to his Medicaid provider agreement, which agreement also obligated Kiely to abide by all applicable federal and state laws.

39. Kiely thus knew, or should have been aware, of the conditions for reimbursement of medical services under both the Medicare and Medicaid programs.

40. While participating as a provider in the Medicare and Medicaid programs, and during the time-frame relevant to the Complaint, Kiely entered into an independent contractor agreement with Bon Secours Hospital in Baltimore, Maryland to render ophthalmological services at its outpatient specialty health care clinic. Under the terms of that agreement, Kiely was responsible for assisting Bon Secours Hospital in the preparation of billing

records and authorized Bon Secours Hospital to submit bills to all applicable payors related to the ophthalmological services performed by him.

The Medically Unnecessary Argon Laser Trabeculoplasties

41. Argon Laser Trabeculoplasty ("ALT") is a medical procedure and is identified for Medicare and Medicaid billing purposes by CPT Code 65855.

42. The ALT is a form of laser surgery where the laser beam is focused on the trabecular meshwork of the eye and a number of burns over 180 (half) to 360 (full) degrees are placed on the meshwork. The laser procedure is utilized in eyes with open angle glaucoma.

43. Glaucoma is a disease of the optic nerve characterized by optic nerve head and visual field damage. Damage to the visual system in glaucoma results from the death of retinal ganglion cells, the axons of which comprise the optic nerve and carry the visual impulses from the eye to the brain, which processes the signals into a visual image.

44. In open angle glaucoma, blockage or malfunction of the trabecular meshwork leads to elevated intraocular pressure ("IOP"). Elevated IOP, an important risk factor for the development and progression of glaucomatous damage, compresses the axons of the nerve cells, causing them to become damaged and eventually die, resulting in permanent visual loss.

45. With open angle glaucoma, the blockage in the trabecular meshwork prevents the flow of fluid from the eye such that it cannot leave the eye as fast as it is produced, causing the fluid to back up. The excess fluid causes increased pressure to build within the eye and the elevated IOP can lead to optic nerve damage.

46. The ALT procedure is a technique utilized to lower the IOP. Laser trabeculoplasty lowers IOP by improving the flow of fluid internally so that it is excreted through the normal drainage pathways of the eye. The purpose of treatment is to prevent further loss of vision by obtaining sustained control of the IOP. The procedure may be divided into two sessions where 180 degrees of the trabecular meshwork is treated in each of the sessions to better gauge the effectiveness of the treatment and limit complications.

47. Repeating the ALT more than two times per eye per patient or performing the procedure on patients who do not even have open angle glaucoma is neither reasonable nor medically necessary.

48. Kiely was aware of the standard regarding the reasonableness and medical necessity of repeat argon laser trabeculoplasties. Upon information and belief, during the time period relevant herein, Kiely attended medical training seminars on the subject taught by experts in the field of ophthalmology.

49. Nevertheless, during the time period relevant herein, Kiely knowingly billed and caused the billing of Medicare and

Medicaid for more than two ALTs per eye per patient regardless of the reasonableness and medical necessity of the billed procedures.

50. Patient records of a number of Kiely's patients for whom ALTs and related health care services were billed to Medicare and Medicaid show that none but the first ALT performed per eye per patient was supported by medical necessity. The number of ALTs that Kiely billed or caused to be billed to Medicare and Medicaid exceeding two per eye per patient were neither reasonable nor medically necessary.

51. A number of different practices engaged in by Kiely contributed to his fraudulent billing of Medicare and Medicaid and caused the submission of false claims by Bon Secours Hospital, which billed the Medicare and Medicaid programs for the services it performed related to the underlying medical procedures performed by Kiely.

52. Patient medical records reveal the absence of a meaningful assessment of the optic nerve to determine the existence, degree, and progression of optic nerve damage, the best measure of glaucoma. There were no drawings of the optic nerve in the records reviewed or photographs of the eye to assess optic nerve damage.

53. Elevated IOP, of itself, is not an indication to repeat the ALT procedure. Neither is loss of visual field. Even where the patient's visual field appeared normal, Kiely performed

repeated ALTs that were not medically necessary.

54. Illustrative is Patient M.B.¹ Between 1999 and 2006, Patient M.B. had 14 ALTs approximately. The only ALT procedure supported by medical necessity was the first such procedure. On March 25, 2003, Patient M.B.'s visual field test was found to be normal. Nonetheless, not more than two weeks later, on April 8, 2003, Patient M.B. received an ALT to the right eye and then on April 15, 2003, Patient M.B.'s left eye was subjected to an ALT. Between June 1, 2004 and June 20, 2006, Patient M.B. received a total of six additional ALTs, three to the right eye and three to the left eye. For Patient M.B., Kiely thus billed and caused the submission of claims to Medicare for at least 8 medically unnecessary ALTs.

55. Set forth below are the multiple dates of service² billed to Medicare, Parts A and B, for Patient M.B.'s medically unnecessary ALTs:

¹ To protect the privacy of the patients referred to herein, each patient is identified by first and last initials. The dates of service, patient initials, and procedures believed to comprise some of the false claims that are the basis of this Complaint have been compiled, along with other pertinent information, into separate Attachments appended to the Complaint.

² These dates of service are included in Attachments A-1A and A-2A to this Complaint, which Attachments set forth some of the false claims believed to have been billed and caused to be billed by Kiely to Medicare during the time period relevant to this Complaint.

Date of Service Billed	CPT Code	Eye Treated	Paid Amount Payor: Medicare Part B	Paid Amount Payor: Medicare Part A
4/8/03	65855	RT(right)	\$229.01	\$620.86
4/15/03	65855	LT (left)	\$229.01	\$641.77
6/1/04	65855	RT(right)	\$248.52	\$578.68
6/8/04	65855	LT (left)	\$248.52	\$578.68
2/15/05	65855	RT(right)	\$223.30	\$671.27
2/22/05	65855	LT (left)	\$223.30	\$626.85
6/13/06	65855	RT(right)	\$224.92	\$805.79
6/20/06	65855	LT (left)	\$224.92	\$745.18

56. For some patients Kiely performed ALTs on both eyes within a week or so of the other. Although glaucoma can be bilateral, it is unusual for patients to have uncontrolled glaucoma in both eyes simultaneously. According to Kiely's medical record entries and billings, nearly every patient manifested uncontrolled bilateral glaucoma.

57. Moreover, Kiely used similar treatment parameters for each ALT treatment for nearly every patient, that is, 80 laser applications at a power of 800 milliwatts, .1 seconds, and 50 microns. When performing an ALT on individual patients, or the same patient, varying the amount of laser energy used and the number of laser bursts to the trabecular meshwork is customary because of variations in the response of the tissue in the eye. Treatment should be performed based upon how the eye appears at the

time, that is, depending upon the shape of the eye and the possible presence of other ocular abnormalities.

58. By way of example, Patient M.B., who received 8 ALTs between April 8, 2003 and June 20, 2006, received the exact same treatment parameters on each visit, as set forth below:

Date of Service Billed	CPT Code	Eye Treated	Laser Bursts	Laser Power
4/8/03	65855	RT(right)	80	800 mw
4/15/03	65855	LT (left)	80	800 mw
6/1/04	65855	RT(right)	80	800 mw
6/8/04	65855	LT (left)	80	800 mw
2/15/05	65855	RT(right)	80	800 mw
2/22/05	65855	LT (left)	80	800 mw
6/13/06	65855	RT(right)	80	800 mw
6/20/06	65855	LT (left)	80	800 mw

59. Similarly, Patient T.B. received 10 ALT procedures between April 8, 2003 and September 20, 2005. As set forth below, the 10 ALTs performed within that period utilized the same treatment parameters as those used for Patient M.B., insofar as the number of laser applications and laser power used:

Date of Service	CPT Code	Eye Treated	Laser Bursts	Laser Power
4/8/03	65855	RT (right)	80	800 mw
4/15/03	65855	LT (left)	80	800 mw
1/20/04	65855	RT (right)	80	800 mw

Date of Service	CPT Code	Eye Treated	Laser Bursts	Laser Power
2/3/04	65855	LT (left)	80	800 mw
7/27/04	65855	RT (right)	80	800 mw
8/3/04	65855	LT (left)	80	800 mw
2/22/05	65855	RT (right)	80	800 mw
3/1/05	65855	LT (left)	80	800 mw
9/13/05	65855	RT (right)	80	800 mw
9/20/05	65855	LT (left)	80	800 mw

60. Prior to April 8, 2003, Patient T.B. had received 4 other ALTs, two per eye. Patient T.B.'s successive 10 ALTs between April 8, 2003 and September 20, 2005, as referenced above, were medically unnecessary.

61. Moreover, certain of Kiely's patients continued to show no sustained positive response to repeated ALT procedures and continued to have uncontrolled IOPs during the course of such treatment, thereby demonstrating the lack of medical necessity of such treatment.

62. Patient M.H.-2 received 12 ALTs between March 25, 2003 and March 21, 2006. Even after two ALTs on each eye, M.H.-2's IOPs continued to be uncontrolled during the course of ALT treatment. Yet Kiely billed 8 ALTs to Medicaid between 9/14/04 and March 21, 2006. The Government alleges that Kiely submitted or caused the submission of the following false claims to Medicaid for medically unnecessary ALTs relative to Patient M.H.-2:

Date of Service Billed	CPT Code	Eye Treated	Paid Amount Payor: Medicaid
9/14/04	65855	RT(right)	\$248.52
9/21/04	65855	LT (left)	\$248.52
1/25/05	65855	RT(right)	\$223.30
2/1/05	65855	LT (left)	\$223.30
8/2/05	65855	RT(right)	\$223.30
8/23/05	65855	LT (left)	\$223.30
3/14/06	65855	RT(right)	\$224.92
3/21/06	65855	LT (left)	\$224.92

63. Patient R.S. was treated by Kiely between August 1998 and April 20, 2004 and received approximately 15 ALTs in that period. Despite the number of ALTs Kiely performed, Patient R.S.'s IOPs were uncontrolled, and R.S. was blind from glaucoma in her right eye. Had Patient R.S. been referred to a physician for surgery known as a trabeculectomy when her initial ALT surgery failed to reduce her IOP, her vision loss in the right eye could have been prevented. The repeated ALT surgeries performed by Kiely were not medically necessary.

64. Kiely, however, knowingly and falsely certified that the successive ALT surgeries for Patient R.S. were medically necessary and reasonable. He thus submitted or caused to be submitted false claims to Medicaid for Patient R.S.'s ALTs, as set forth below:

Date of Service Billed	CPT Code	Paid Amount Payor: Medicaid
3/11/03	65855	\$270.00
3/18/03	65855	\$270.00
4/20/04	65855	\$270.00
4/27/04	65855	\$270.00

65. Kiely thus billed and caused the submission of false claims to Medicare on multiple dates of service as set forth above in paragraphs 55, 59, 60, 62 and 64 for medically unnecessary ALTs that he certified were reasonable and medically necessary, a certification that had a natural tendency to influence Medicare's and Medicaid's decision to reimburse, that is, pay for the procedures.

66. More examples of the false claims that Kiely knowingly submitted or caused to be submitted to Medicare and Medicaid for the payment of medically unnecessary ALTs that would not have been reimbursed by Medicare or Medicaid in the absence of the certification of medical necessity are appended to the Complaint in Attachments A-1, A-2, and A-3, which Attachments³ identify those false claims submitted to Medicare Part B, Medicare Part A, and Medicaid, respectively, during the time period relevant herein.

³ Attachments A-1A, A-2A, and A-3A identify the patients by their first and last initials for privacy purposes and the Attachments further contain information relating to the date of service and procedure codes at issue herein and the amount paid for the submitted claim by payor.

67. The Government reserves the right to further supplement this Complaint with additional false claims for medically unnecessary ALTs submitted and caused to be submitted by Kiely and further reserves the right to demonstrate such through discovery and at trial.

The Non-Rendered and Medically Unnecessary Lysis of Adhesions

68. A Yag Capsulotomy, identified for billing purposes as CPT Code 66821, is a laser procedure that addresses a complication of cataract surgery. Cataract surgery removes the cloudy lens causing blurred vision from the lens capsule. An artificial lens called an intraocular lens is inserted into the capsule to replace the natural lens. The capsule may become cloudy or wrinkled after cataract surgery and again cause blurred vision that may impede normal functioning.

69. A Yag Capsulotomy creates an incision in the posterior capsule behind the intraocular lens implant. The incision allows the posterior capsule to retract to aid the passage of light to the retina.

70. To assist providers in determining when and whether Yag Capsulotomies will be reimbursed, Trailblazer, the carrier that processed provider claims for Medicare during the time period relevant to this Complaint, issued a Local Coverage Determination ("LCD") that specified that reimbursement for a YAG Capsulotomy would be denied if the diagnosis, frequency, or documentation did

not support medical necessity. The LCD, which, upon information and belief, predated and was in effect during the time period relevant to this Complaint, also stated clearly that "[i]f procedure 66821 is billed more than once on the same eye of the same patient, documentation must be submitted with the claim before payment may be made." An indication of medical necessity is visual loss.

71. A Lysis of Adhesion ("LOA") is a laser procedure identified for billing purposes by CPT Code 65860. It too addresses a complication of cataract surgery, but the complication is considered rare. The procedure is performed when the iris becomes effectively stuck to the intraocular lens capsule first inserted during a cataract removal procedure; the LOA removes the adhesion and reshapes the iris.

72. The LOA procedure is used rarely and ordinarily when the patient is having a problem with vision. It usually does not have to be done more than once per eye.

73. Billing data showed that between January 1, 2000 and November 30, 2004, Kiely billed CPT Code 65860, signifying the performance of the LOA procedure, approximately 1,140 times. The second most frequent biller of that CPT Code, in the State of Maryland, billed 65860 only 63 times between 2000 and 2005.

74. Certain of the medical records for Kiely's patients who purportedly received LOAs are absent of clinical evidence that the

procedure was actually performed.

75. Kiely's operative notes indicated that he performed a Yag Capsulotomy rather than the LOA billed to Medicare and Medicaid, and the operative notes did not even identify what adhesions were purportedly being lysed.

76. Moreover, the LOA procedure was invariably billed for both eyes. Despite the fact that the LOA is usually done only once per eye, the procedure was billed more than twice per eye per patient for certain of Kiely's patients.

77. Illustrative in this regard is Patient D.J. Between April 4, 2000 and July 13, 2004, Medicare Part B was billed for 6 LOA procedures, three for the right eye and three for the left eye, respectively, as set forth below:

Date of Service Billed	CPT Code Billed	Eye Identified	Paid Amount: Medicare Part B
4/4/2000	65860	LT (left)	\$187.76
4/11/2000	65860	RT (right)	\$187.76
5/15/2001	65860	LT (left)	\$203.78
5/22/2001	65860	RT (right)	\$203.78
7/6/2004	65860	RT (right)	\$213.76
7/13/2004	65860	LT (left)	\$213.76

78. Kiely knowingly and falsely billed Medicare Part B for at least two LOA procedures for dates of service on July 6, 2004 and July 13, 2004 that were not performed and even if performed,

were not medically necessary. Medicaid was billed for those same two dates of service and paid \$53.44 for each, or a total of \$106.88.

79. Another example is Patient I.H. Between November 28, 2000 and December 17, 2002, Medicare Part B was billed for 8 LOAs, four for the right eye and four for the left eye, as set forth below:

Date of Service Billed	CPT Code Billed	Eye Identified	Paid Amount: Medicare Part B
11/28/2000	65860	RT (right)	\$187.76
12/12/2000	65860	LT (left)	\$187.76
9/18/2001	65860	RT (right)	\$203.78
9/25/2001	65860	LT (left)	\$203.78
4/9/2002	65860	RT (right)	\$204.27
4/16/2002	65860	LT (left)	\$204.27
12/10/2002	65860	RT (right)	\$204.27
12/17/02	65860	LT (left)	\$204.27

80. Kiely knowingly and falsely billed Medicare Part B for at least two LOAs for dates of service on December 10, 2002 and December 17, 2002 that were not performed and even if performed, were not medically necessary. Medicaid was billed for those same dates of service and paid \$51.07 for each of the two dates of service billed, or a total of \$102.14.

81. Kiely's false or fraudulent claims damaged the United States because the false claims resulted in the payment of monies that would not have been paid.

82. More examples of the false claims that Kiely knowingly submitted or caused to be submitted to Medicare and Medicaid for the payment of LOAs that were not performed, and even if performed were not medically necessary, are appended to the Complaint in Attachments B-1 and B-2, which Attachments⁴ identify those false claims submitted to Medicare Part B and Medicaid, respectively, during the time period relevant herein.

83. The Government reserves the right to further supplement this Complaint with additional false claims for non-performed and medically unnecessary LOAs submitted and caused to be submitted by Kiely and further reserves the right to demonstrate such through discovery and at trial.

COUNT ONE
PRESENTING FALSE CLAIMS
(False Claims Act, 31 U.S.C. § 3729(a)(1))

84. The United States realleges and incorporates herein by reference paragraphs 1 through 83.

85. With respect to the patients identified in this Complaint, the Defendant knowingly presented or caused to be

⁴ Attachments B-1 and B-2 identify the patients by their first and last initials for privacy purposes and the Attachments further contain information relating to the date of service and procedure codes at issue herein and the amount paid for the submitted claim by payor.

presented false or fraudulent claims to the United States for payment or approval. These false or fraudulent claims were presented or caused to be presented to Medicare Parts A and B and Medicaid for the payment of CPT codes 65855 ("Argon Laser Trabeculoplasty") and 65860 ("Lysis of Adhesion").

86. Each of the claims for payment submitted or caused to be submitted by the Defendant for each procedure identified in this Complaint is a separate false or fraudulent claim.

87. As described above in paragraphs 1 through 83, the claims identified in this Complaint were false or fraudulent because they were claims for reimbursement for medical services that were (1) medically unnecessary, and (2) were not rendered as described in the claim for payment.

88. The Defendant, with respect to each false or fraudulent claim that he presented or caused to be presented, knew such claims were false or acted in deliberate ignorance or reckless disregard of the falsity of the claims.

89. As a result of the false or fraudulent claims presented or caused to be presented by the Defendant, the United States, through Medicare Parts A and B and Medicaid, paid the claims and thereby sustained damages and the United States is entitled to statutory damages under the False Claims Act in an amount to be determined at trial, plus a civil penalty for each false claim.

COUNT TWO
MAKING OR USING A FALSE RECORD OR STATEMENT
(False Claims Act, 31 U.S.C. § 3729(a)(2))

90. The United States realleges and incorporates herein by reference paragraphs 1 through 89.

91. With respect to the patients identified in this Complaint, the Defendant knowingly made or caused to be made false records to get a false or fraudulent claim paid by the United States through Medicare Parts A and B and Medicaid.

92. The claims for payment identified in this Complaint were false records because they were claims for medically unnecessary services and medical services that were not rendered as described in the claims for payment.

93. As a result of the false record made or caused to be made by the Defendant, the United States paid the claims and is therefore entitled to statutory damages under the False Claims Act, in an amount to be determined at trial, plus a civil penalty for each false claim.

COUNT THREE
COMMON LAW FRAUD

94. The United States realleges and incorporates by reference paragraphs 1 through 93.

95. The false or fraudulent claims identified in this Complaint that the Defendant submitted or caused to be submitted to Medicare Parts A and B and Medicaid constituted misrepresentations of material fact.

96. The Defendant knew that his misrepresentation, both direct and implied, that the claims for payment submitted or caused to be submitted to Medicare Parts A and B and Medicaid were for medically necessary services and were actually performed as described, were false.

97. These misrepresentations were material. The submission of only those claims which are for medically necessary services and services that were performed as described in the claim are conditions for reimbursement.

98. The Defendant knew that the United States would rely, and intended the United States to rely, upon these false representations.

99. The United States reasonably relied upon the false claims submitted or caused to be submitted by the Defendant.

100. As a result of the Defendant's false representations, the United States has been damaged in an amount to be determined at trial.

COUNT FOUR
UNJUST ENRICHMENT

101. The United States incorporates by reference the allegations contained in paragraphs 1 through 100.

102. The United States, through its carriers, directly and indirectly, paid the Defendant for claims that were for services that were not medically necessary and performed as described and for which the Defendant was thereby unjustly enriched. In paying

the claims that the Defendant submitted, the United States conferred a benefit on the Defendant.

103. The Defendant knew or should have known that he was receiving reimbursements on the basis of false or fraudulent claims and therefore in violation of the conditions for payment prescribed by the Medicare and Medicaid programs as described above in paragraphs 22, 24, 29 and 33 above.

104. Defendant's acceptance and retention of reimbursements based upon the false or fraudulent claims make it inequitable for him to retain the benefit or value of the reimbursements paid to him by the United States.

105. By causing the United States to reimburse claims for falsely or fraudulently billed services, and by the receipt of those federal funds, Defendant has been unjustly enriched and is liable to pay such amounts, which will be determined at trial, to the United States.

COUNT FIVE
PAYMENT BY MISTAKE

106. The United States realleges and incorporates herein paragraphs 1 through 105.

107. The United States, through its carriers, directly and indirectly, paid the Defendant for claims that were for services that were not medically necessary and performed as described. The false representations and records made by the Defendant concerning the medical necessity of the services billed to Medicare Part B

and Medicaid and the actual performance of the services billed to those programs were material to the United States's determination to reimburse the Defendant for the services billed.

108. The United States would not have paid for the claims relevant to this Complaint had it known that the medical services billed in the claims were not medically necessary or performed as described.

109. The United States relied upon the representations and records made by the Defendant concerning the medical necessity and actual performance of the medical services billed to Medicare Part B and Medicaid and paid the claims, thereby resulting in damages to the United States in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff, the United States of America demands that judgment be entered in its favor and against the Defendant as follows:

A. On Count One (Knowingly Presenting or Causing Presentment of False Claims), judgment against the Defendant for treble the amount of damages, as established at trial, plus a penalty of \$5,500 to \$11,000 per false claim as established at trial;

B. On Count Two (Knowingly Making or Using A False or Fraudulent Record), judgment against the Defendant for treble the amount of damages, as established at trial, plus a penalty of \$5,500 to \$11,000 per false claim as established at trial;

C. On Count Three (Common Law Fraud), judgment against the Defendant for Plaintiff's damages as established at trial;

D. On Count Four (Unjust Enrichment), judgment against the Defendant for Plaintiff's damages as established at trial, plus interest;

E. On Count Five (Payment by Mistake), judgment against the Defendant for Plaintiff's damages as established at trial, plus interest;

F. Disgorgement by the Defendant of all interest, earnings, and profits obtained fraudulently from Medicare and Medicaid between October 29, 2002 through April 14, 2009 and appropriate injunctive relief, including but not limited to remedies under the Federal Debt Collection Procedures Act, 28 U.S.C. § 3001, *et seq.*;

G. In addition to the relief requested in paragraphs A through F, the Plaintiff requests that the Defendant be assessed pre-judgment interest from the date of the first false claim, as established at trial, and that Plaintiff be given any other relief

that is deemed just, proper, and appropriate by the Court.

Respectfully submitted,

Rod J. Rosenstein
United States Attorney

By: /s/
Tarra DeShields
Roann Nichols
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(410) 209-4800 (tele.)
(410) 962-9947 (fax)
Counsel for the United States

PRAYER FOR JURY TRIAL

The United States of America requests a jury trial in this action.

Respectfully submitted,

Rod J. Rosenstein
United States Attorney

By: /s/
Tarra DeShields
Roann Nichols
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Counsel for the United States

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 18th day of July, 2011, a copy of the United States's First Amended Complaint was filed electronically and served, by certified mail, on Steve Allen, Esquire, Hodes, Pessin & Katz, P.A., 901 Dulaney Valley Road, Suite 400, Towson, Maryland 21204.

/s/
TARRA DeSHIELDS
Assistant United States Attorney